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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/776,913 | 02/06/2001 | Hyman M. Schipper | S&B-C048 | 3680 |

30132 7590 03/24/2004

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| EXAMINER | |
|---|---|
| WINSTON, RANDALL O | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1654 | |

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/776,913 | SCHIPPER ET AL. | |
| | Examiner | Art Unit | |
| | Randall Winston | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *2-14 and 21-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-14 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Acknowledgement is made of receipt and entry of the amendment filed on December 23, 2003.

Claims 2-14 and 21-23 are under examination.

The objection under 37 CFR 1.75(c) has been overcome by Applicant's amendment.

The rejection made under 35 U.S.C. 112, second paragraph, has been overcome by Applicant's amendment.

### *Claim Rejections - 35 USC § 102*

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 2 and 23 as amended stands rejected under 35 U.S.C. 102(e) as being anticipated by Perrella et al. (US 5,888,982).

Applicant argues that the methods disclosed by Perrella et al. rely on the discovery of elevated levels of the HO-1 in the vascular tissue of the patient compared to a normal control is an indication that the patient maybe at risk of developing or suffering from sepsis-associated hypotension whereas the claimed invention focuses on

the evaluation of H0-1 as systemic biological indicator of a dementing disease at various stages of development which is predicated on distinctly different biochemical and physiological findings compared to sepsis-associated hypotension. Therefore, applicant submits that Perrella et al. relied on by the examiner does not provide enabling disclose sufficient to arrive at the claimed invention. Applicant argument is not found persuasive because since Perrella et al. teach the same means and/or method of using a commercial package for assessing a dementing disease (see, e.g. examiner's non-final 35 U.S.C. 102(e) rejection) as of the claimed invention's means and/or method, Perrellas et al. anticipates the claimed invention no matter if Perrella et al. do not provide sufficient disclosure to arrive at the claimed invention.

Applicant also argues that as in the present case, the "printed matter" conveys a novel method for obtaining a desired result and the method is essential for operation of the components of the package, then the printed matter must be considered. Applicant argument is not found persuasive because as examiner explained in its non-final rejection under 35 U.S.C. 102(e), that is legally well established that printed matter- - e.g., providing instruction to a known product, to show its intended use does not lend patentable distinction to the product, per se-i.e., a well known compound, packaged and labeled to show its new use, is not patentable (see, e.g., In re Haller, 73 USPQ 403). Therefore, the printed instructions showing intended use fail to lend patentable distinction to the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-14 and 21-23 as amended stands rejected under 35 U.S.C. 103(a) as unpatentable over Perrella et al.

Applicant argues that examiner has not articulated explicit or factual findings on motivation or suggestion to combine the elements disclosed in the prior art to arrive at the applicant's invention and thus support a 35 U.S.C. 103 ground of rejection. Applicant argument is not found persuasive because as examiner explains in its non-final office action, the primary reference is relied upon for the reasons discussed above. Although not expressly taught, the adjustment of these and other conventional working conditions (e.g., placing well known agents within a commercial package such as a vail or a kit), is deemed merely a matter of judicial selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art the time the invention was made, especially in the absence of evidence to the contrary.

**No claims are allowed.**

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Brenda Brumback

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SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600